

19

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

HELM, et al.

Appln. No.: 09/133,766

Confirmation No.: 6988

Filed: August 12, 1998

For: ALLERGEN/INFLAMMATORY TESTING AND DIAGNOSIS



Group Art Unit: 1644

Examiner: Ronald B. Schwadron

RECEIVED  
MAR 19 2002  
TECH CENTER 1600/2900

**REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Office Action dated December 18, 2001, please consider the remarks as submitted herewith.

Claims 34-43 are all the claims pending in the application

**REMARKS**

In paragraph no. 3 of the Office Action, the Examiner rejected claims 34-43 under 35 U.S.C. 112, first paragraph. The Examiner asserted that the claims are too broad, and, therefore are not enabled.

More specifically, the Examiner appears to believe that the working example is not representative of the invention as claimed. The Examiner appears to assert that the recitation of a "mast cell-line and /or basophil cell-line" is too broad, and should be limited to the RBL-2H3

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111  
U.S. Serial No.: 09/133,766

cell line transfected with at least the alpha chain of the human high-affinity receptor for IgE. As a result of the Examiner's belief that the cell line used in the example is not representative of a broader class of cell lines, the Examiner also appears to take the position that the recitation of an allergen, generally, and of a general cellular response thereto are also too broad.

For the following reasons, the rejection is traversed, respectfully.

First, as the Examiner knows, the breadth of a claim does not, in itself, cause the claim to be non-enabled. That is, breadth and enablement are separate issues.

Second, as the Examiner also knows, the entire specification, not just the working examples, is relevant to the determination of enablement.

Finally, the specification is to be read in light of the knowledge of one of ordinary skill in the art as of the effective US filing date.

In the present case, while the claims are broader than the specific materials used in the working example, they are not broader than what one of ordinary skill in the art as of the effective filing date, would consider to be enabled by the working example, the teachings of the specification and the skill and knowledge in the art. This is explained in more detail below with reference to the declaration of Dr. Birgit Helm, in which Dr. Helm explains how one of ordinary skill in the art would have interpreted the present specification, in its entirety, with respect to enablement.

The Applicant refutes the Examiner's conclusion that there is no disclosure that the invention can be practiced with any mast cell line or basophil cell line on the basis that one

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111  
U.S. Serial No.: 09/133,766

skilled in the art, on reading the application, would understand that the experimentation set forth in the specification is representative of the broadly claimed invention.

Additionally, or alternatively, the Applicant refutes this conclusion on the basis that one skilled in the art, on reading the application, would define the invention as set forth in the claims despite the limited experimentation.

The Applicant bases this reasoning on the following facts which the Applicant requests the Examiner consider in conjunction with the declaration filed herewith and executed by Birgit Helm, the inventor and a person familiar with the knowledge of one of ordinary skill in the art as of the November 25, 1993, filing date of the present application.

The Applicant submits that at the time the original application was filed, those skilled in the art were generally aware of the fact that Rat Basophil Leukaemia cell lines were homologues of a class of cell lines of mast cell or basophil origin. The RBL-2H3 cell line represented one specific example of the class.

These cell lines are characterized not only by their origin, but also by their functionality. They possess the basic machinery of mast cells or basophils and, importantly, this machinery is configured so that they respond in a predictable manner when exposed to a mast cell or basophil trigger. In other words, for all intents and purposes they behave as mast cells or basophils. This means they represent useful tools for elucidating the cell biology of mast cells and basophils.

There was, and is, no reason to believe that the RBL-2H3 cell line would not function in the same way as other homologous cell lines.

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111  
U.S. Serial No.: 09/133,766

For this reason, it is submitted that one of ordinary skill in the art, upon reading that the method taught in the above application could be used to identify the allergenicity of a substance, would immediately realize that the methodology described on pages 9-19 could be undertaken using homologous cell lines. Indeed, there would be no reason for him to think otherwise because all the background art has taught him that that is what he should expect.

Similarly, it is also submitted that one of ordinary skill in the art when considering the nature of the invention (i.e. the teaching that mast cell or basophil cell lines can be used to identify IgE independent cell mediator release) would know that this mediator release would be exhibited by homologous cell lines and so consider that the nature of the invention lay in this knowledge and not the one, meagre, tool used to elucidate it.

The fact that the Applicant has since shown that other homologous cell lines can be used to work the invention merely demonstrates what those skilled in the art had already known.

Accordingly, the Applicant submits that the reference in the claims to cell lines of mast cell or basophil origin merely represents an equitable scope of protection having regard to the common general knowledge of those skilled in the art and the teaching of the invention.

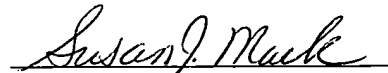
Applicant, therefore, respectfully requests that the Examiner reconsider his position and remove the rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. § 1.111  
U.S. Serial No.: 09/133,766

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

  
Susan J. Mack  
Registration No. 30,951

SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

Date: March 18, 2002